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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/630,626 | 07/30/2003 | Gregory A. Demopulos | PH.1.0037.US2 | 9065 |

7590 10/03/2005

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| EXAMINER | |
|---|---|
| SINGH, JAI P | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1616 | |

DATE MAILED: 10/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/630,626 | DEMOPULOS ET AL. | |
| | Examiner | Art Unit | |
| | Jai P. Singh | 1616 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) 1-54 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-54 are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.



SDD

## DETAILED ACTION

Claims 1 - 54 are pending.

### *Election/Restrictions*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1 to 22 and 28 are drawn to a method for perioperatively inhibiting inflammation, inhibiting pain effecting mydriasis, and decreasing intraocular pressure during an ophthalmologic procedure, comprising continuously irrigating ocular tissues during an ophthalmic procedure with a solution including at least first and second agent selected from anti-inflammatory agents, analgesic agents mydriatic agents and agents for decreasing intraocular pressure (IOP reducing agents), classified in class 424, subclass 422; class 514, subclasses 817, 816 and 818.

II. Claims 23 to 27 and 29 to 54 are drawn to a perioperative solution for use during ophthalmologic procedures to inhibit inflammation, inhibit pain, effect mydriasis or decrease intraocular pressure during the procedures, including at least first and second agents being selected from anti-inflammatory agents, analgesic agents, mydriatic agents and agents for decreasing intraocular pressure (IOP reducing agents), classified in class 424, subclass 422; class 514 and subclasses 912, 914, 915, 952 and 954.

Inventions in group I and group II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the anti-inflammatory agents are used in post surgical pain relief and pain management. The pain relief can be obtained by a balanced approach to pain management by employing combination of non-steroidal anti-inflammatory drugs in combination of anesthetics, narcotics/opiod. Similarly, local anesthetics helps in relieving pain by injecting these near the site of incision after surgery. This also protects the surgical site by reducing the bacterial infection. On the other hand, topical anesthetics are also used in an ointment or cream and applied directly onto the surface of skin or around the painful area.

These inventions are distinct, each from the other because of different type of agents such as anti-inflammatory agents (steroid and non-steroidal anti-inflammatory drugs) and belong to separate class of compounds. Similarly, analgesics, and anesthetics agents are also different and belong to different class of compounds. Additionally, anti-inflammatory agents can be used in relieving inflammation in other applications such as dermatological disorders. To perform searches and evaluate prior art in other uses/applications of these agents (first and second agent) either in solution form or in any other form will be

extensive and will be an undue burden for the examiner. Further, to search and examine arts related with anti-inflammatory agents, analgesics, anesthetics, mydriasis and IOP reducing agents as single use or in several combinations thereof will be an additional burden for the examiner, specially when these agents have wide variety of applications.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species of the claimed invention: In the instant application, group I consisting of claims 1-22 and 28 are directed to the method for perioperatively inhibiting inflammation, inhibiting pain, effecting mydriasis and decreasing intraocular pressure during and ophthalmic procedure with a solution including at least first and second agents being selected from the physiologic functional classes of anti-inflammatory agents, analgesic agents, mydriatic agents and agents for decreasing intraocular pressure (IOP reducing agents). Similarly, group II consisting of claims 23-27 and 29-54 are drawn to a perioperative solutions for use during ophthalmologic procedures to inhibit inflammation, inhibit pain, effect mydriasis or decrease intraocular pressure during the procedures, including at least first and second agents being selected from anti-inflammatory agents, analgesic agents, mydriatic agents and agents for decreasing intraocular pressure (IOP reducing agents). Both group I and group II comprised of several

specific agents, e.g., anti-inflammatory agents comprises of steroid, non-steroidal anti-inflammatory drugs containing specific compounds in claims 2, 3, 30 and 31; analgesic agents such as local anesthetics and opioids containing specific compounds in claims 4, 5, 32 and 33; mydriatic agents in containing specific agents in claims 6, 7, 34 and 35 and IOP reducing agents containing specific compounds in claims 8, 9, 36 and 37. In addition to these, the claims containing combination of different agents are also found to be generic (see claims 17-22 and 44-49). Similarly, the solutions in claims from 23 to 27 and 50 to 54 are also generic).

Claims 1-22 and 28 are drawn in regards to method claims (group I) containing different agents (first and second agents) as well as solution claims 23-27 and 29-54 (group II) indicated above. If applicant elect a method group I then applicant must select a single species, for search purposes, containing single specific first agent and a single specific second agents to be elected for the method of inhibiting perioperative inflammation defining all features of the inventions in the application. If applicant elect group II for examination for the solution used during ophthalmic procedures then applicant must select a single specific solution, for search puposes, containing specific ingredients in combination which defines all features of the solution in the invention. In addition to this if the solution combination is selected, then this must contain one single combination claimed in the invention which defines all features of the claimed invention.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

A telephone call was made to Ms. Marcia S. Kelbon on September 22, 2005 to discuss the possibility of categorizing the inventions in separate group such as method and solution containing specific species. At this time no election was made and restriction requirement was requested.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jai P. Singh whose telephone number is 571-272-8147. The examiner can normally be reached on M-F from 830 AM to 5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

jps
9/23/05

S. Qazi

SABIHA QAZI, PH.D
PRIMARY EXAMINER